**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**
**AT CHARLESTON**

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| **IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION**<br><br>**THIS DOCUMENT RELATES TO:**<br><br>**ALL PLAINTIFFS LISTED IN PLAINTIFFS' MOTION** | **Master File No. 2:12-MD-02327**<br>**MDL 2327**<br><br>**JOSEPH R. GOODWIN**<br>**U.S. DISTRICT JUDGE** |

**ETHICON'S MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE CERTAIN OPINIONS AND TESTIMONY OF JOSEPH CARBONE, M.D.**

Joseph Carbone, M.D. is a board-certified urogynecologist who has performed hundreds of suburethral mesh slings and prolapse reconstructions with mesh devices, treated mesh complications, and performed mesh removals. Dr. Carbone also has educated and trained hundreds of surgeons in these mesh techniques and has, throughout his career, kept abreast of issues in his field by review and study of the relevant literature.

Despite this extensive career, Plaintiffs seek to exclude Dr. Carbone's opinions that: (1) the benefits of TVT and Prolift outweigh their risks based, in part, on the incidence of complications with polypropylene transvaginal mesh devices that he sees in his practice; (2) the Instructions for Use (IFU) for TVT and Prolift adequately warn of their risks; and (3) the designs of TVT and Prolift are safe and effective for use in patients. Plaintiffs' motion should be denied because:

- **Dr. Carbone's clinical experience supports his risk/benefits opinions.** Dr. Carbone's extensive clinical experience, including his observations of the incidence of complications he sees in his practice, supports his opinion that the benefits of TVT and Prolift outweigh their risks.

- **Dr. Carbone is qualified to offer the challenged opinions.** Dr. Carbone's extensive training, experience, and review of the relevant medical literature qualify him to offer opinions on the safety and efficacy of the TVT and Prolift, as well as for the IFUs for these devices.

- **Dr. Carbone's design opinions are the result of a reliable methodology.** Clinical experience and review of relevant literature are reliable methods for forming opinions on the safety and efficacy of TVT and Prolift.

Plaintiffs' challenges to Dr. Carbone's opinion testimony are meritless under Rule 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). Defendants Ethicon, Inc. and Johnson & Johnson (Ethicon) therefore ask that Plaintiffs' motion be denied.

## ARGUMENTS AND AUTHORITIES

### I. Dr. Carbone's Clinical Experience with TVT and Prolift Supports His Opinion on the Safety and Efficacy of These Products.

A physician's "knowledge, experience, and review of scientific literature provide sufficiently reliable bases for his opinions under *Daubert*." *Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 714 (S.D.W. Va. 2014). This Court in particular has made clear that a physician can draw upon his clinical experience and review of relevant literature to give an opinion on the risk/benefit profile of polypropylene mesh. *Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *7 (S.D.W. Va. Apr. 24, 2015).

Dr. Carbone seeks to offer that same kind of opinion here—*i.e.*, that the benefits of the TVT and Prolift products outweigh their risks, and he bases that opinion on his extensive clinical experience and review of the relevant medical literature over the course of his career. Ex. B to Pls.' Mot. (Dkt. 2025-2), Carbone TVT Report at 1-3, 15-25; Ex. C to Pls.' Mot. (Dkt. 2025-3), Carbone Prolift Report at 1-3, 10-25, 28-36; Ex. 1, Carbone Reliance List; Ex. 2, Carbone 3/16/16 TVT Dep. Tr. 26:17-24, 27:10-23; Ex. 3, Carbone 3/17/16 TVT Dep. Tr. 114:14-23, 124:6-125:6. That career includes specializing in female pelvic-reconstructive surgery for over

20 years as a board-certified urogynecologist. Ex. B to Pls.' Mot. (Dkt. 2025-2), Carbone TVT Report at 1; Ex. C to Pls.' Mot. (Dkt. 2025-3), Carbone Prolift Report at 1.

Indeed, Dr. Carbone trained in residency under Dr. Carl Klutke in some of the earliest uses of transvaginal mesh for the treatment of stress urinary incontinence (SUI) in the United States, and also completed a fellowship with female pelvic-reconstructive surgeon, Dr. Shlomo Raz. Ex. B to Pls.' Mot. (Dkt. 2025-2), Carbone TVT Report at 1-2; Ex. C to Pls.' Mot. (Dkt. 2025-3), Carbone Prolift Report at 1-2. He has performed hundreds of suburethral mesh-sling procedures and prolapse reconstructions with nonmesh and mesh techniques, and has successfully performed the Prolift technique without any major complications. Ex. B to Pls.' Mot. (Dkt. 2025-2), Carbone TVT Report at 2; Ex. C to Pls.' Mot. (Dkt. 2025-3), Carbone Prolift Report at 2. He keeps current with the medical literature on the use of mesh and has been reviewing the relevant medical literature since 1998 when he was first introduced to mesh. Ex. 2, Carbone 3/16/16 TVT Dep. Tr. 26:17-24. And he trains and educates hundreds of surgeons in the treatment of incontinence and prolapse surgeries using the retropubic, obturator, single incision, and abbreviated obturator slings, as well as the Prolift device. Ex. B to Pls.' Mot. (Dkt. 2025-2), Carbone TVT Report at 2-3; Ex. C to Pls.' Mot. (Dkt. 2025-3), Carbone Prolift Report at 2-3.

In his clinical practice, Dr. Carbone treats mesh complications, and has performed approximately 40 or 50 removals of mesh products. Ex. 2, Carbone 3/16/16 TVT Dep. Tr. 132:19-133:20. Those removals involved primarily Ethicon mesh products that had to be removed due to erosion. *Id.* at 133:17-20; Ex. 3, Carbone 3/17/16 TVT Dep. Tr. 51:9-17. To classify this data, Dr. Carbone's office manager reviewed ICD-9 and ICD-10 (International Classification of Diseases) coding to determine how many of his patients experienced erosion from polypropylene transvaginal mesh devices over the years. Ex. 3, Carbone 3/17/16 TVT Dep.

Tr. 109:22-110:9. Based on the information gathered, Dr. Carbone concluded that his complications rate was slightly lower than is reported in the medical literature. *Id.* at 110:10-22.

Plaintiffs take issue with Dr. Carbone's complication-rate opinion because it is not backed by any survey, statistics or a formal study, but Plaintiffs provide no support that this is required under *Daubert*. Instead, what *Daubert* requires, and what Dr. Carbone did here, was to take the patients in his practice that have experienced mesh-related complications, classify them as they were ICD-coded, and then reach a conclusion based on that data. This is a reliable methodology that supports his risk/benefit and complication-rate opinions, and is consistent with the analysis this Court employs for reliability. *Winebarger*, 2015 WL 1887222, at *7. Indeed, this Court has rejected the argument that opinions on mesh complications are unreliable because they are based on personal experience and review of medical literature. *See Eghnayem*, 57 F. Supp. 3d at 714 (denying request to exclude Dr. Walmsley's general opinions on complication rates based on his personal clinical experience and review of the medical literature). And although this Court has excluded the complicate-rate opinion of a plaintiffs' expert, Dr. Margolis, it did so because his complication-rate opinion was contrary to the medical literature and he gave "no scientific basis for disagreeing with [those] studies." *Sanchez v. Boston Scientific Corp.*, No. 2:12-CV-05762, 2014 WL 4851989, at *12-13 (S.D.W. Va. Sept. 29, 2014) (finding that "[w]ithout further explanation for his disagreement with these studies, Dr. Margolis's method is unreliable").

That is not the case here. Unlike Dr. Margolis, Dr. Carbone does not disagree with the medical literature. Dr. Carbone instead testified that his complication rates were only a "little bit lower" than some of the rates in the literature. Ex. 3, Carbone 3/17/16 TVT Dep. Tr. 110:10-111:2. He also explained *why* this was the case—*i.e.*, he has a unique, small-town patient

population where he is the only female pelvic reconstructive surgeon and is able to provide the "first and best" surgeries without "dealing with re-operations." *Id.* at 111:3-23.

Nor do Plaintiffs explain why Dr. Carbone's methodology is unreliable because he is unfamiliar with the follow-up rates for patients of other physicians in his area. *See* Pls.' Mem. (Dkt. 2027) at 7. This testimony has no bearing on the admissibility of Dr. Carbone's risk/benefit and complication-rate opinions and is, at best, a point to be made during cross examination. Even so, Dr. Carbone testified that his patient follow-up rate is "pretty high" in rural southern Virginia, where he is the only female pelvic medicine reconstructive surgeon. Ex. 3, Carbone 3/17/16 TVT Dep. Tr. 111:14-112:7.

Lastly, there is no Rule 26 violation as Plaintiffs argue. Dr. Carbone's report is replete with statements about complications and complication rates, and opinions associated with those statements and their bases. This disclosure sufficiently apprises Plaintiffs of Dr. Carbone's opinions and does not run afoul of Rule 26.

At bottom, Dr. Carbone is sufficiently qualified and the opinions he seeks to offer result from a reliable methodology. It would make no sense, and is contrary to the Rules of Evidence, to allow an expert to draw upon clinical experience and medical literature to provide a risk/benefit opinion, but then prevent that expert from explaining to the jury how he reached that opinion.

## II. Dr. Carbone Is Qualified to Provide an Opinion on the Adequacy of the TVT and Prolift IFUs.

"[D]octors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings." *Winebarger*, 2015 WL 1887222, at *15. A urogynecologist, in particular, is qualified to make a comparison between "the risks he perceives that the [device]

poses to patients" and whether the labels "convey these risks to physicians." *Id.* (finding Dr. Shull qualified to give opinions on product labeling based on his clinical experience because his testimony did not touch on regulatory issues).

Dr. Carbone seeks to offer such an opinion here. In addition to his clinical experience with mesh techniques and review of IFUs, Dr. Carbone relies on his review of complications reported in the medical literature, statements of leading medical societies, discussions with other surgeons, and his general knowledge as a pelvic-floor surgeon. Ex. 2, Carbone 3/16/16 TVT Dep. Tr. 123:18-25; Ex. 3, Carbone 3/17/16 TVT Dep. Tr. 63:3-9, 113:21-114:23, 121:1-13, 128:21-129:22. Based on this support, Dr. Carbone has formed the opinion that risks other than erosion—including pain, dyspareunia, infection, urinary problems, recurrent incontinence, bleeding, organ perforation, neuro-muscular problems, scarring, mesh contraction, roping, curling, degradation, and cytotoxicity—either do not occur, or are known risks of pelvic surgery and not attributable to the mesh product. Ex. B to Pls.' Mot. (Dkt. 2025-2), Carbone TVT Report at 20; Ex. C to Pls.' Mot. (Dkt. 2025-3), Carbone Prolift Report at 18-25; Ex. 2, Carbone 3/16/16 TVT Dep. Tr. 106:4-107:18; Ex. 3, Carbone 3/17/16 TVT Dep. Tr. 112:20-113:11.

Accordingly, Dr. Carbone concludes that there are no additional unique risks of the TVT and Prolift devices that should be included in the IFUs. Ex. 2, Carbone 3/16/16 TVT Dep. Tr. 128:2-12, 129:22-130:4; Ex. 3, Carbone 3/17/16 TVT Dep. Tr. 113:5-7, 113:21-114:4; Ex. C to Pls.' Mot. (Dkt. 2025-3), Carbone Prolift Report at 24, 28-29. Dr. Carbone's opinion is consistent with the legal principle that there is no duty to warn of risks commonly known to surgeons who use the device. 21 C.F.R. § 801.109(c) (explaining that information may be omitted from labeling for prescription device "if, but only if, the article is a device for which directions, hazards, warnings and other information are commonly known to practitioners licensed by law to use the device").

This Court's rulings in *Tyree* and *Bellew* are distinguishable. In those cases, the Court excluded testimony from defense experts who offered opinions that the warnings were adequate merely because they included risks that the experts observed in their own practices. *See Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 584 (S.D.W. Va. 2014), as amended (Oct. 29, 2014); *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, Dkt. 265 at 33 (S.D.W. Va. Nov. 20, 2014). While a single physician's experience may not be sufficient, it is sound methodology to rely upon a large pool of scientific literature and studies, combined with the clinical experience and evaluation of many physicians and medical organizations, to support a conclusion that certain risks do not occur and therefore need not be included in the IFU, as Dr. Carbone has done here. Indeed, when Plaintiffs' experts have concluded that risks do occur based on such support, they are allowed to testify that the risk should have been included in the mesh warnings. It stands to reason that an expert employing this same methodology, while reaching a different conclusion, has also provided admissible testimony. That Plaintiffs may disagree with Dr. Carbone's conclusion goes to weight, not admissibility.

Dr. Carbone is "uniquely an expert regarding the warning statements" based on his review of IFUs and teaching other physicians. Ex. 3, Carbone 3/17/16 TVT Dep. Tr. 63:3-9; *see also* Ex. 2, Carbone 3/16/16 TVT Dep. Tr. 123:18-25. Based on his clinical perspective and review of the medical literature, he is qualified to give opinions about warnings. He need not be familiar with FDA rules or regulations to give this testimony. *Winebarger*, 2015 WL 1887222, at *6-7, 15; *see also Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 703, 719 (S.D.W. Va. 2014) (Drs. Rosenzweig and Blaivas adequately experienced physicians to testify to risks of surgery and whether the risks were addressed in the IFU despite lack of expertise in FDA regulations or standards governing device warnings); *Trevino v. Boston Scientific Corp.*, 2:13-cv-01617, 2016

WL 1718836, at *13-14 (S.D.W. Va. Apr. 28, 2016) (Dr. Shull permitted to testify on adequacy of DFUs "from a clinical perspective"). Plaintiffs' arguments to the contrary should be rejected.

At bottom, Dr. Carbone is qualified to provide opinions on the IFUs and has employed a sufficiently reliable methodology. His opinion on the adequacy of the Prolift and TVT IFUs is therefore admissible.

## III. Dr. Carbone's Opinions on the Safety and Efficacy of the Designs of TVT and Prolift Are Admissible.

### A. Dr. Carbone Is Qualified to Provide Safety and Efficacy Opinions.

A urogynecologist's "extensive experience with pelvic floor disorders and the use of mesh to treat such disorders qualifies him to render opinions on [product design], notwithstanding his lack of expertise in the particular areas of product design or biomaterials." *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 612 (S.D.W. Va. 2013) (finding Dr. Shull qualified, but excluding his design opinion on reliability grounds). Further, a physician's "experience removing polypropylene transvaginal mesh devices and performing revision and excision procedures qualifies him" to give product design opinions. *Winebarger*, 2015 WL 1887222, at *6 (emphasis removed).

Dr. Carbone is qualified to opine that the design of TVT and Prolift is safe and effective for use in patients based on his clinical experience performing hundreds of suburethral mesh sling placements and removing mesh devices from patients. Ex. B to Pls.' Mot. (Dkt. 2025-2), Carbone TVT Report at 2; Ex. C to Pls.' Mot. (Dkt. 2025-3), Carbone Prolift Report at 2; Ex. 2, Carbone 3/16/16 TVT Dep. Tr. 56:6-58:11, 132:24-133:16. Although he is not a "company" design expert, Dr. Carbone is well-versed on the clinical properties of mesh and qualified by experience to give opinions on those properties. Ex. 2, Carbone 3/16/16 TVT Dep. Tr. 79:2-14. He is not required to be more to give an opinion on the safety and efficacy of the mesh products

he uses or considers for use. *In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 612; *Winebarger*, 2015 WL 1887222, at *6.

### B. Dr. Carbone Utilized a Reliable Methodology in Forming His Safety and Efficacy Opinions.

As stated, it is an acceptable methodology for a physician to draw upon his clinical experience and review of relevant literature when forming opinions on the risk/benefit profile of polypropylene mesh. *Winebarger*, 2015 WL 1887222, at *7.

Dr. Carbone used this scientifically reliable methodology here. In addition to his clinical experience, Dr. Carbone's opinion is supported by his training, review of Level 1 medical literature (including the Cochrane review comparing native tissue repairs to the mesh products, SGS article comparing the two as well as the risks, and a number of other studies that corroborate those findings), teaching and learning about pelvic mesh, discussions with other surgeons, and interactions with physicians, patients, and engineers. Ex. 2, Carbone 3/16/16 TVT Dep. Tr. 90:6-17; Ex. 3, Carbone 3/17/16 TVT Dep. Tr. 121:1-13, 124:6-125:6, 128:2-19; Ex. B to Pls.' Mot. (Dkt. 2025-2), Carbone TVT Report at 15-25; Ex. C to Pls.' Mot. (Dkt. 2025-3), Carbone Prolift Report at 10-36; Ex. 1, Carbone Reliance List.

There is no requirement under *Daubert* that Dr. Carbone review internal company design documents for his methodology to be reliable as Plaintiffs argue. Nor has this Court ever required as much. Although Plaintiffs rely on *Winebarger* to support their argument, that reliance is misplaced. In that case, Dr. Shull sought to opine that the company had failed to follow its own internal protocols and that those protocols were lacking, even though he had never seen any standard operating procedures for the company's medical device development or any of the internal design protocols. *Winebarger*, 2015 WL 1887222, at *14. Dr. Shull's methodology was thus lacking "a necessary piece of data" and unreliable "regardless of the literature he has

reviewed or the experience he has gained" because his methodology failed to include a review of the documents that would support his internal-protocols opinion. *Id.*

By contrast, Dr. Carbone here is not attempting to testify that Ethicon followed its own internal design protocols or that they were otherwise adequate. Accordingly, his opinion does not require a review of internal design protocols. As Dr. Carbone explained, he would know the clinical effect of any design change on the safety or efficacy because it would be reflected in the medical literature he reviewed. Ex. 4, Carbone 3/16/16 Prolift Dep. Tr. 74:22-75:18.

Plaintiffs set forth a number of additional points that do not undermine Dr. Carbone's qualifications or methodology, including that (1) Ethicon did not ask him to help design a mesh product; (2) he only used Ethicon mesh products; (3) he did not review Dr. Ulmsten's contract; (4) he is not familiar with milestone payments; and (5) he does not know who Christian Falconer is. *See* Pls.' Mem. (Dkt. 2027) at 12-17. Plaintiffs do not and cannot explain how these statements have any bearing on the *Daubert* analysis for the admissibility of Dr. Carbone's testimony. While these may be points for cross examination, they do not lead to exclusion of Dr. Carbone's design opinions.

The same is true of Plaintiffs' argument that Dr. Carbone allegedly "could not answer" whether the mesh could cause pain or dyspareunia. *See id.* at 12. Dr. Carbone testified that the mesh itself does not cause pain or dyspareunia, but that the pelvic surgery could cause those symptoms. Ex. 3, Carbone 3/17/16 TVT Dep. Tr. 112:20-113:11. There is nothing in that statement that offends *Daubert*. It is merely Dr. Carbone's conclusion. And the reliability inquiry under *Daubert* does not concern itself with an expert's conclusions, only the expert's methodology.

At bottom, Dr. Carbone has the expertise required to provide opinions on the safety and efficacy of the TVT and Prolift designs, and has provided reliable bases for those opinions. His opinion testimony is admissible.

**CONCLUSION**

For the foregoing reasons, Ethicon respectfully requests that Plaintiffs' motion be denied in its entirety.

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I certify that on May 9, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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